Biotechnology in Agriculture Confronts Agreements in the WTO

The recent introduction of agricultural products produced through biotechnology has given rise to new trade disputes. These disputes could test the adequacy of the science-based frameworks provided by the SPS and TBT agreements to resolve biotechnology issues. *[David R. Kelch (dkelch@econ.ag.gov), Mark Simone, and Mary Lisa Madell (mlmadell@email.aphis.usda.gov)[1]]*

Trade disputes have surfaced over labeling of genetically modified organisms (GMOs) and the differing regulatory approval systems among countries. The disputes will likely continue as new GMOs are introduced onto the world market. The Sanitary and Phytosanitary (SPS) Agreement and the Technical Barriers to Trade (TBT) Agreement in the WTO provide guidelines for developing regulations based on science. While scientists in importing and exporting countries have found the GMOs safe, some consumer and environmental groups, particularly in the 15-member European Union (EU), have pressured their governments into regulatory procedures and labeling of GMOs that have disrupted corn trade already and look to do so again in the future. Bilateral consultations have not resolved the issue and the EU is further assessing the environmental impact of large volumes of seeds before final approval is granted--even though their scientific committees have approved the varieties in question. While the United States exhausts the bilateral process of consultation and negotiation, it remains to be seen whether the SPS and TBT Agreements provide enough guidance to settle the disputes raised by the introduction of GMOs.

Importance to the United States

The ability to genetically manipulate organisms to produce desirable crop traits that can benefit producers, consumers, and the environment, will likely revolutionize the production and marketing of agriculture and food products worldwide. U.S. multinational companies are among the leading developers of genetically modified crop varieties—especially export crops such as corn, soybeans, and cotton—and U.S. producers of these crops are adopting this new technology at a rapid rate. The acceptance of GMOs in the world market is critical for the future prosperity of U.S. producers of corn, soybeans, and cotton, and for the companies that provide the technology, because of these crops' dependence on exports.

The European Union's (EU) reaction to consumers' and environmentalists' concerns about GM crops led to a mandate to label foods that contain GMOs, and Japan has also proposed a labeling regulation for GMOs. EU consumers have suffered a sequence of food-borne diseases, the last of which was the "mad cow" disaster that shook the faith of EU consumers in their scientists to the core.

Environmentalists in the EU are convinced that the long-term effects of GMOs are unknown and cast doubt on EU scientific findings to the contrary. Treading warily, the EU Commission has instituted a lengthy and exhaustive regulatory system for approval of GMOs that has proven to be a barrier to the timely flow of traded goods. The EU's relatively prolonged approval of U.S. varieties of GM corn in 1998 led to a loss of around $200 million for U.S. exporters.[2] Currently, the SPS and TBT Agreements of the Uruguay Round provide guidelines for bilateral negotiations on developing regulations and labeling, but the Agreements may not be satisfactory to the EU, or other countries, to settle disputes in their current form because the agreements specify that regulations and labeling be science-based, which does not take into account religious and ethical beliefs of some people or other citizens who do not accept the judgement of scientists.

The Regulatory Issue

GMOs have been successfully and rapidly introduced into agriculture in the United States, in part because the U.S. regulatory system was prepared to treat these products like conventional products for risk assessment and safety purposes. In 1986, the U.S. government adopted a "Coordinated Framework" for regulating biotechnology-derived products in response to public and industry concerns about food and environmental safety and quality. This streamlined regulatory process was designed to ensure that all aspects of public safety were covered. Because of the "Coordinated Framework" approach, the United States has been able to regulate GMOs through existing legislation and regulatory agencies based on the principle that biotechnology-derived products are not fundamentally different from other products in terms of safety evaluation, therefore, existing regulations are appropriate and adequate. And only final products and their intended uses would be subject to regulation, not the method of production, although methods are regulated for worker and environmental safety.[3]

[1]Mary Lisa Madell is a trade policy analyst with the Animal and Plant Health Inspection Service (APHIS) of USDA.

[2]An estimate by the Foreign Agricultural Service of USDA.

[3]Caswell, Margriet F., Keith O. Fuglie, and Cassandra A. Klotz. Agricultural Biotechnology: An Economic Perspective. AER No. 687. ERS, USDA. May 1994.

In contrast, the EU has a separate regulatory system for GMOs, regulates both process and product, and its regulatory approval takes two to three times as long as the system in the United States. The United States was shut out of its traditional Spanish market for corn because the EU was unable to approve the U.S. Bt corn varieties in the time frame required. The same problem will likely occur in 1999 and in the foreseeable future if new U.S. GM varieties of corn enter export channels to the EU. The dispute will continue because it is not likely the EU will have approved any of the new varieties in time for U.S. imports and new varieties cannot be separated from varieties already approved without incurring significantly higher costs.

The Labeling Issue

Labeling is not required by the United States if the U.S. regulatory system finds that there is no fundamental difference between the GMO varieties and the non-GMO varieties. Labeling in the United States is only required if there is a significant difference between the conventional and the GM product. For example, if there is a significant difference in nutritional components, the label would indicate this difference—not that the product was produced through biotechnology.

The EU labeling requirement for GMOs does not have a scientific basis to require a label. The EU's own scientific committees agree that the GMOs currently imported are safe for consumption and the environment. The EU's stated justification is "to provide consumers with information that they want." Accurate labeling of products that contain GMOs at an appropriately specified threshold level will be technically difficult. Moreover, GMOs are inputs in a very large number of both food and feed products, making the labeling issue even more complicated. A label will likely be construed as "negative" by the consumer even though GMOs have been approved by scientific bodies. The EU's mandatory labeling requirement is opposed by the United States and by U.S. exporters to the EU because of the unsubstantiated scientific basis and impractical aspects of the legislation.

The WTO and Non-tariff Trade Barriers

GMOs were not a trade issue when the SPS and TBT Agreements were negotiated in 1994. How then might the rights and obligations of the SPS Agreement relate to trade in GMOs? One of the first things to consider is whether there are international standards applicable to GMOs. Under the SPS Agreement, if a country bases its measures on applicable international standards, those measures are presumed to be in compliance with the SPS Agreement. While countries are not obligated to adopt international standards as their own measures, they don't violate the SPS Agreement if their measures are based on an international standard. A country may choose to impose a measure that is not based on an international standard, even if it provides a higher level of protection, if there is a scientific justification.

Currently, there are no international standards that specifically govern GMOs nor is there a harmonization of regulatory approaches mandated, although the SPS and TBT Agreements have spurred counties to modify their regulatory systems. Also, the OECD is in the process of attempting to provide a process that will allow its member countries to harmonize their regulatory approaches for GMOs. The International Plant Protection Convention (IPPC) covers plant health and the environment but doesn't make any distinctions between traditionally developed products and GMOs.

There aren't any international standards for the length of time that a risk assessment takes, or for the regulatory process for adopting SPS measures, or for how much public comment is appropriate as part of the process. The recent problems over trade in GMOs with the EU have centered around its regulatory process, which has been criticized as being slow, cumbersome, insufficiently transparent, and subject to political manipulation. The SPS and TBT Agreements specify transparency of regulations as a requirement for approval systems but these transparency provisions have yet to be tested in an official dispute proceeding.

Labeling and Regulatory Processes Under the TBT and SPS Agreements

The TBT Agreement governs technical regulations and standards, including packaging, marking and labeling requirements, and procedures for the assessment of conformity. The disciplines of the both the SPS and TBT Agreements are designed to prevent technical regulations from creating unnecessary and arbitrary obstacles to international trade, and require that such regulations be no more restrictive than necessary. To date it has not been determined whether the EU's mandated labeling directive or its slow and non-transparent approval system for GMOs comprise technical regulations that create "unnecessary obstacles" to trade.

While regulatory systems and labeling requirements are to be based on science according to the SPS and TBT agreements, considerations such as religious and ethical convictions or lack of trust in science/scientists to justify labeling and the way regulatory bodies function may have to be addressed. At this point it remains to be seen whether further elaboration on the both TBT and SPS Agreements will have to take place to resolve these issues.